

REMARKS

In the Official Action dated February 25, 2003, claim 30 has been objected to as allegedly containing sequences that are not referred to by reference to the identification number of an entered sequence. Claims 21 and 35 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by United States Patent No. 5,171,838 to Chiba et al., Moreland et al. (1996) *Arthritis and Rheumatism* 39(9):S244, Panayi et al. (1996) *Arthritis and Rheumatism* 39(9):S244, Connolly et al. (1996) *Arthritis and Rheumatism* 39(9):S245, Wending et al. (1996) *Arthritis and Rheumatism* 39(9):S245 and Reece et al. (1996) *Arthritis and Rheumatism* 39(9):S245. Claim 21 has also been rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enabling support. The specification has been objected to because of alleged informalities and the Abstract of the Disclosure has been objected to pursuant to MPEP §608.01(b).

This response addresses each of the Examiner's objections and rejections. Accordingly, the application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The specification has been objected to as allegedly containing informalities. In response, Applicants have amended the specification to correct the alleged informalities. Accordingly, the objections are overcome and withdrawal thereof is respectfully requested. In addition, Applicants have corrected the Abstract of the Disclosure consistent with the provisions of MPEP §608.01(b).

Claim 30 has been objected to allegedly containing sequences that are not referred to by reference to the identification number of an entered sequence. In response, Applicants have amended claim 30 to insert appropriate SEQ ID NOS. Accordingly, the rejection of claim 30 is overcome and withdrawal thereof is respectfully requested.

Claims 21 and 35 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by United States Patent No. 5,171,838, Moreland, Panayi et al., Choy et al., Connolly et al., Wending et al. and Reece et al. The Examiner alleges that claims are drawn to antibodies against IL-16 inhibitory peptides comprising X-L-L-X. The Examiner contends that the cited references teach various antibodies that react with CD4 and that each of these antibodies would bind a soluble CD4 molecule, thus meeting the limitations of claims 21 and 35. In response, and in an effort to expedite favorable prosecution, Applicants have amended claim 21 and canceled claim 35, without prejudice. Claim 21, as amended, is directed to a pharmaceutical composition comprising the antibody of any one of claims 29 to 33, which claims recite antibodies against specified peptide sequences that are neither taught nor suggested by any one of the cited references. Accordingly, the rejection of claims 21 and 35 under 35 U.S.C. §102(b) is overcome and withdrawal thereof is respectfully requested.

The Examiner has rejected claim 21 under 35 U.S.C. §112, first paragraph as allegedly lacking enabling support. The Examiner admits that the specification is enabling for pharmaceutical compositions comprising the 4162W94 antibody. The Examiner contends that the specification does not reasonably provide enablement for pharmaceutical compositions of antibodies against CD4 or regions thereof. The Examiner further alleges that the Applicant has not provided teachings that would allow one of skill in the art to predictably use the claimed

composition to treat any disease or condition, noting diseases that are set forth on page 32, such as Rheumatoid Arthritis and Inflammatory Bowel Disease.

In response, Applicants respectfully direct the Examiner's attention to Yoshimoto et al. (2000) *Blood* 95(9):2869-2874, attached hereto as Exhibit 1, which demonstrates that antibodies to IL-16 significantly suppress Delayed Type Hypersensitivity (DTH). DTH is a TH1 cytokine immune response analogous to Rheumatoid Arthritis and Inflammatory Bowel Disease. "Delayed Type Hypersensitivity" (DTH) is the typical *in vivo* manifestation of the cell-mediated immunity", see p. 2869, left column. Notably, anti IL-16 antibodies significantly suppressed foot pad swelling induced by an antigen challenge, together with decreased infiltration of leukocytes into the DTH foot pads of mice.

Furthermore, the Examiner's attention is respectfully directed to Keates et al. (2000) *Gastroenterology* 119:972-982 (attached as Exhibit 2) which provides further evidence that IL-16 antibodies and pharmaceutical compositions comprising such antibodies are efficacious in treating diseases. Keates et al. confirm that anti-IL-16 antibodies significantly reduce weight loss, mucosal ulceration, colonic injury and inflammation in mice. Accordingly, both Yoshimoto and Keates provide irrefutable evidence that therapeutic results are predictably achieved, without undue experimentation, with pharmaceutical compositions containing antibodies to IL-16 of the present invention. Accordingly, the rejection of claim 21 under 35 U.S.C. §112, first paragraph is overcome and withdrawal thereof is respectfully requested.

Thus, in view of the foregoing amendments and remarks, the application is in condition for allowance which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Bernstein', with a long horizontal flourish extending to the right.

Peter I. Bernstein
Registration No. 43,497

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

PIB:dg